

SULFOXAFLOR (252)

First draft was prepared by Dr Paul Humphrey, Australian Pesticides and Veterinary Medicines Authority, Canberra, Australia

EXPLANATION

Sulfoxaflor is the first member of the novel sulfoximine class of insecticides. It controls insects via a unique interaction with the insect nicotinic acetylcholine receptor and has a broad lack of cross-resistance to other insecticides.

Sulfoxaflor was evaluated by JMPR in 2011. An ADI and AfRD of 0–0.05 mg/kg bw and 0.3 mg/kg bw respectively were established by the 2011 Meeting. A residue definition of *sulfoxaflor* was established for both compliance and dietary risk assessment in both plant and animal commodities.

After the subsequent meeting of CCPR, the proposed MRLs for citrus fruits, pome fruits, stone fruits and tree nuts were held at Step 4 because the GAP reviewed by JMPR differed from the registered USA GAP.

The Meeting received information on registered use patterns in pome fruit, stone fruit, citrus fruit and tree nuts in Australia and the USA. The residue trial data submitted to the 2011 Meeting for these crops was reconsidered against the registered GAPs.

USE PATTERN

Information on registered uses made available to this Meeting is shown in Table 1.

Table 1 Registered uses of sulfoxaflor on citrus fruits, pome fruits, stone fruits and tree nuts

Crop	Country	Formulation		Application					PHI [days]	
		g ai/L or [g ai/kg]	Type	Method	Timing [Interval - days]	Rate [g ai/ha]	Concentration [g ai/100 L]	Maximum [g ai/ha/year] or (no. per crop)		
Citrus Fruits										
Citrus, including oranges, lemons, grapefruit, limes, mandarins and tangerines	Australia	240	SC	Foliar	—	—	9.6	192 g ai/ha/single application (2)	1	
Citrus (Crop Group 10) including citrus citron, grapefruit, kumquat, lemon, lime, orange, tangelo, tangerines and hybrids of these	USA	[500]	WG	Foliar	14	96	—	298 g ai/ha/year (4)	1	
Pome Fruits										
Pome fruit, including apples, pears and nashi	Australia	240	SC	Foliar	—	—	9.6	192 g ai/ha/single application (2)	7	
Pome fruits (Crop Group 11) including apples, crabapple, loquat, mayhaw, pears, quince	USA	[500]	WG	Foliar	7	96	—	298 g ai/ha/year (4)	7	
Stone Fruits										
Stone fruit, including apricots, cherries, nectarines, peaches and plums	Australia	240	SC	Foliar	—	—	7.2	144 g ai/ha/single application (2)	7	

Crop	Country	Formulation		Application					PHI [days]
		g ai/L or [g ai/kg]	Type	Method	Timing [Interval - days]	Rate [g ai/ha]	Concentration [g ai/100 L]	Maximum [g ai/ha/year] or (no. per crop)	
Stone fruits (Crop Group 12) including apricot, nectarine, peach, plum, prune, sweet cherry, tart cherry	USA	[500]	WG	Foliar	7	96	–	298 g ai/ha/year (4)	7
Tree Nuts									
Tree nuts (Crop Group 14) including almonds, cashew, chestnut, filbert (hazelnut), macadamia nut, pecan, walnut	USA	[500]	WG	Foliar	7	96	–	298 g ai/ha/year (4)	7

RESIDUES RESULTING FROM SUPERVISED TRIALS

The Meeting received no new information on residues resulting from supervised trials.

The citrus fruits, pome fruits, stone fruits and tree nuts data evaluated at JMPR 2011 which are tabulated below, were also evaluated for this appraisal, with reference to the submitted labels showing registered uses for these crops in Australia and the USA. The tables of residues data have been taken essentially unaltered from the 2011 evaluation, but with the addition of a column in the citrus, pome and stone fruits tables expressing the applied active as grams per 100 L, as well as *g ai/ha*, to enable easier comparison with Australian GAP for citrus, pome and stone fruits, which are expressed as concentrations. In addition, when two trials were performed at the same location in the same year and differ only by variety of fruit or nut, they have been separated by a dotted line in the tables and the highest residue from one trial only has been used in the estimation of an MRL and STMR.

Group	Commodity	Country	Table No.
FC Citrus Fruits	Grapefruit	USA	2
	Lemons	USA	3
	Oranges	Australia, Brazil, USA	4
	Mandarins	Australia	5
FP Pome Fruits	Apples	Australia, New Zealand, Europe,	6
	Pears	Australia, Europe, USA	7
FS Stone Fruits	Cherry	Australia, New Zealand, Europe,	8
	Nectarines	Australia, New Zealand	9
	Peach	Australia, New Zealand, Europe,	10
	Apricot	Australia, New Zealand	11
	Plums	Australia, USA	12
TN Tree Nuts	Almonds	USA	13
	Pecans	USA	14
Animal feeds	Almond hulls	USA	15

*Citrus fruits**Grapefruit*

Table 2 USA residue trials for grapefruit

Location Year	Variety	Application				RTI	DAT	Portion	Residues (mg/kg)		
		No.	g ai/ha	g ai/100L	L/ha				Sulfoxaflor	X11719474	X11721061
De Leon Springs, FL, USA, 2010	Star red	2	202	19.0	1060	7	0 1 7 13	Whole fruit	0.059 0.012 0.010 < 0.01	< 0.01 < 0.01 < 0.01 < 0.01	< 0.01 < 0.01 < 0.01 < 0.01
De Leon Springs, FL, USA, 2010	Ruby red	2	202	19.0	1060	7	0 1 7 13	Whole fruit	0.088 0.013 < 0.01 < 0.01	< 0.01 < 0.01 < 0.01 < 0.01	< 0.01 < 0.01 < 0.01 < 0.01
Fort Pierce, FL, USA, 2010	Star red	2	202	19.0	1060	7	0 1 7 13	Whole fruit	0.076 0.010 < 0.01 < 0.01	< 0.01 < 0.01 < 0.01 < 0.01	< 0.01 < 0.01 < 0.01 < 0.01
Fort Pierce, FL, USA, 2010	Ruby red	2	202	19.0	1060	7	1 1 1	Whole fruit Peel Pulp	< 0.01 0.050 < 0.01	< 0.01 < 0.01 < 0.01	< 0.01 < 0.01 < 0.01
Vero Beach, FL, USA 2010	White	2	202	19.0	1060	7	1	Whole fruit	0.016	< 0.01	< 0.01
Edinburg, TX, USA 2010	Rio red	2	202	19.4	1040	7	1 1 1	Whole fruit Peel Pulp	0.13 0.79 < 0.01	< 0.01 < 0.01 < 0.01	< 0.01 < 0.01 < 0.01
San Luis Obispo, CA, USA 2010	Not specified	2	202	15.2	1330	7	0 1 7 14 0 1 7 14 0 1 7 14	Whole fruit Peel Pulp	0.029 0.024 < 0.01 < 0.01 < 0.01 0.081 0.065 0.039 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	< 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	< 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01
Springville, CA, USA 2010	Oro blanco	2	202	16.1	1250	7	1	Whole fruit	0.11	< 0.01	< 0.01

Lemons

Table 3 USA residue trials in lemons

Location Year	Variety	Application				RTI	DAT	Portion	Residues (mg/kg)		
		No.	g ai/ha	g ai/100L	L/ha				Sulfoxaflor	X11719474	X11721061
Ft. Pierce, FL, USA, 2010	Bears	2	202	19.1	1060	7	1	Whole fruit	0.11	< 0.01	< 0.01
San Luis Obispo, CA, USA, 2010	Lisbon	2	202	20.0	1010	7	0 1 7 14	Whole fruit	0.081 0.028 0.040 0.031	< 0.01 < 0.01 < 0.01 < 0.01	< 0.01 < 0.01 < 0.01 < 0.01

Location Year	Variety	Application				RTI	DAT	Portion	Residues (mg/kg)		
		No.	g ai/ha	g ai/100L	L/ha				Sulfoxaflor	X11719474	X11721061
San Luis Obispo, CA, USA, 2010	Lisbon	2	202	21.2	950	7	0	Whole fruit	0.072	< 0.01	< 0.01
							1		0.051	< 0.01	< 0.01
							7		0.083	< 0.01	< 0.01
							14		0.014	< 0.01	< 0.01
Porterville, CA, USA, 2010	Improved meyer	2	202	16.2	1250	8	0	Whole fruit	0.31	< 0.01	< 0.01
							1		0.29	< 0.01	< 0.01
							8		0.20	< 0.01	< 0.01
							15		0.16	< 0.01	< 0.01
Maricopa, CA, USA 2009	Lisbon	2	202	20.6	980	6	1	Whole fruit	< 0.01	< 0.01	< 0.01
Bakersfield, CA, USA 2009	Lisbon	2	202	21.2	1050	6	1	Whole fruit	< 0.01	< 0.01	< 0.01

Oranges

Table 4 Residue trials in Australia, Brazil and the USA for oranges

Location Year	Variety	Application				RTI	DAT	Portion	Residues (mg/kg)		
		No.	g ai/ha	g ai/100L	L/ha				Sulfoxaflor	X11719474	X11721061
Gayndah, Queensland, Australia, 2008	Valencia "Honey Balls"	2	192	20.2	950	7	0	Whole fruit	0.47	< 0.01	< 0.01
							1		0.41	0.01	< 0.01
							7		0.35	< 0.01	< 0.01
							14		0.29	0.01	0.01
		4	96	8.82	1090	7	0		0.41	0.01	0.02
							1		0.37	< 0.01	0.01
							7		0.32	< 0.01	0.01
							14		0.30	< 0.01	0.02
Waikerie, South Australia, Australia, 2008	Valencia	2	192	9.6	2000	7	1	Whole fruit	0.33	< 0.01	< 0.01
		4	94	4.7	2000	7	7	Whole fruit	0.18	0.02	< 0.02
Cobram, Victoria, Australia, 2008	Navel "Summer Navel"	2	192	9.6	2000	7	1	Whole fruit	0.09	< 0.01	< 0.01
		4	96	4.8	2000	7	7	Whole fruit	0.02	< 0.01	< 0.01
Tocumwal, New South Wales, Australia, 2009	Valencia	2	193	6.43	3000	7	1	Whole fruit	0.16	< 0.01	< 0.01
Mangrove Mountain, New South Wales, Australia, 2010	Valencia	2	191	7.64	2500	7	1	Whole fruit	0.15	< 0.01	< 0.01
Ramco, South Australia, Australia	Valencia	2	194	7.76	2500	7	1	Whole fruit	0.43	0.010	< 0.01

		Application							Residues (mg/kg)		
Location Year	Variety	No	g ai/ha	g ai/100L	L/ha	RTI	DAT	Portion	Sulfoxaflor	X11719474	X11721061
Mogi Mirim, SP, Brazil, 2008	Pera Coroa	2	200	10	2000	7	0	Whole fruit	0.11	< 0.01	< 0.01
							1		0.099	< 0.01	< 0.01
							3		0.010	0.010	< 0.01
							7		0.068	< 0.01	< 0.01
							14		0.057	< 0.01	< 0.01
							28		0.062	< 0.01	< 0.01
							0	Juice	0.025	< 0.01	< 0.01
							1		0.013	< 0.01	< 0.01
							3		0.012	< 0.01	< 0.01
							7		0.018	< 0.01	< 0.01
							14		< 0.01	< 0.01	< 0.01
							28		< 0.01	< 0.01	< 0.01
							0	Peel	0.52	0.032	0.015
							1		0.55	0.038	0.019
							3		0.37	0.032	0.014
							7		0.38	0.062	0.036
							14		0.18	0.030	0.026
							28		0.085	0.021	0.015
Piracicaba, SP, Brazil, 2008	Valencia	2	200	9.99	2000	7	1	Whole fruit	0.096	< 0.01	< 0.01
							7		Juice	0.061	< 0.01
							1	Peel	0.026	< 0.01	< 0.01
							7		< 0.01	< 0.01	< 0.01
							1		0.52	0.012	< 0.01
7	0.21	0.010	< 0.01								
Ibiraci, MG, Brazil, 2008	Pera Rio	2	200	10	2000	7	1	Whole fruit	0.28	0.012	< 0.01
							7		Juice	0.21	0.040
							1	Peel	< 0.01	< 0.01	< 0.01
							7		< 0.01	< 0.01	< 0.01
							1		1.3	0.075	0.026
7	0.69	0.10	0.044								
Rolandia, PR, Brazil, 2008	Valencia	2	200	10	2000	7	1	Whole fruit	0.12	< 0.01	< 0.01
							7		Juice	0.11	0.015
							1	Peel	< 0.01	< 0.01	< 0.01
							7		< 0.01	< 0.01	< 0.01
							1		0.58	0.31	0.026
7	0.29	0.051	0.023								
De Leon Springs, FL, USA, 2008	Navel	2	202	18.9	1070	7	0	Whole fruit	0.11	< 0.01	< 0.01
							1		0.074	< 0.01	< 0.01
							7		0.060	< 0.01	< 0.01
							15		0.051	< 0.01	< 0.01
26	0.044	< 0.01	< 0.01								
De Leon Springs, FL, USA, 2010	Hamlin	2 ^a	198	18.7	1060	7	1	Whole fruit	0.11	< 0.01	< 0.01
									0.082	< 0.01	< 0.01
		2 ^b	194	18.5	1050	7	7	Whole fruit	0.082	< 0.01	< 0.01
DeLeon Springs, FL, USA, 2010	Valencia	2	202	15.3	1320	7	1	Whole fruit	0.16	< 0.01	< 0.01
						7			< 0.01	< 0.01	< 0.01
DeLeon Springs, FL, USA, 2010	MidSweet	2	202	15.4	1320	7	1	Whole fruit	0.085	< 0.01	< 0.01
						7			0.011	< 0.01	< 0.01
Kathleen, FL, USA, 2008-2009	Hamlin	2 ^a	203	18.7	1090	7	1	Whole fruit	0.12	< 0.01	< 0.01
		2 ^b	202	18.5	1090	7	7	Whole fruit	0.11	< 0.01	< 0.01
Vero Beach, FL, USA, 2008	Hamlin	2 ^c	203	18.9	1080	7	1	Whole fruit	0.12	< 0.01	< 0.01
		2 ^d	203	18.9	1080	7	7	Whole fruit	0.099	< 0.01	< 0.01
Fort Pierce, FL, USA, 2008	Hamlin	2 ^a	206	18.5	1110	7	1	Whole fruit	0.093	< 0.01	< 0.01
		2 ^b	201	18.4	1090	7	7	Whole fruit	0.047	< 0.01	< 0.01
Edinburg, TX, USA, 2009	Valencia	2	203	20.2	1000	7	1	Whole fruit	0.098	< 0.01	< 0.01
						7			0.23	< 0.01	< 0.01
Sanger, CA, USA, 2009	Washington Navel	2	202	6.45	3130	7	1	Whole fruit	0.062	< 0.01	< 0.01
						6			0.036	< 0.01	< 0.01

Location Year	Variety	Application				RTI	DAT	Portion	Residues (mg/kg)		
		No	g ai/ha	g ai/100L	L/ha				Sulfoxaflor	X11719474	X11721061
Sanger, CA, USA, 2008	Valencia	2	202	15.8	1280	7	1 7	Whole fruit	0.050 0.041	< 0.01 < 0.01	< 0.01 < 0.01
Mount Dora, FL, USA, 2010	Hamlin	2	202	15.4	1310	7	1 7	Whole fruit	0.12 0.020	< 0.01 < 0.01	< 0.01 < 0.01
San Louis, Obispo, CA, USA, 2010	Valencia	2	202	18.6	1090	7	1 7	Whole fruit	0.038 < 0.01	< 0.01 < 0.01	< 0.01 < 0.01

^a Both applications used non-ionic surfactant at 0.05% (v/v)

^b Both applications used crop oil concentrate at 1% (v/v)

^c Application #1 used non-ionic surfactant at 0.05% (v/v), while application #2 used citrus oil at 1% (v/v).

^d Application #1 used citrus oil at 1% (v/v), while application #2 used non-ionic surfactant at 0.05% (v/v).

Mandarins

Table 5 Residue trials for sulfoxaflor in mandarins (Australian trials)

Location Year	Variety	Application				RTI	DAT	Portion	Residues (mg/kg)		
		No	g ai/ha	g ai/100L	L/ha				Sulfoxaflor	X11719474	X11721061
Gayndah, Queensland, Australia, 2010	Imperials	2	148	7.59	1950	7	0 1 7 14	Whole fruit	0.45 <u>0.44</u> 0.40 0.32	< 0.01 < 0.01 < 0.01 0.01	< 0.01 0.009 0.01 0.02
Wallaville, Queensland, Australia, 2008	Murcott	2	192	9.6	2000	7	1	Whole fruit	<u>0.15</u>	< 0.01	< 0.01
		4	95	4.8	2000	7	7	Whole fruit	0.18	< 0.01	< 0.01
Wallaville, Queensland, Australia, 2010	Imperials	2	191	7.64	2500	7	1	Whole fruit	<u>0.28</u>	< 0.01	< 0.01
Mundubbera, Queensland, Australia, 2010	Imperials	2	192	9.6	2000	7	1	Whole fruit	<u>0.34</u>	< 0.01	< 0.01

Pome fruits

Apples

Table 6 Residue trials for sulfoxaflor in apples (Australia, New Zealand, Europe, and USA)

Location Year	Variety	Application				RTI	DAT	Portion	Residues (mg/kg)		
		No	g ai/ha	g ai/100L	L/ha				Sulfoxaflor	X11719474	X11721061
Orange, New South Wales, Australia, 2008	Red Delicious	2	195	10.3	1900	7	3 7 14 28	whole fruit	0.22 <u>0.19</u> 0.14 0.08	< 0.01 < 0.01 < 0.01 < 0.01	< 0.01 < 0.01 < 0.01 < 0.01
		4	98	4.9	2000	7	3 7 14 28		0.21 0.15 0.10 0.11	< 0.01 < 0.01 < 0.01 < 0.01	< 0.01 0.010 < 0.01 0.010
Lenswood, Australia, 2008	Fuji	2	164	9.11	1800	8	7	whole fruit	<u>0.14</u>	< 0.01	< 0.01

Location Year	Variety	Application				RTI	DAT	Portion	Residues (mg/kg)		
		No	g ai/ha	g ai/100L	L/ha				Sulfoxaflor	X11719474	X11721061
		4	81	4.5	1800	7	7	whole fruit	0.09	< 0.01	< 0.01
Havelock North, New Zealand, 2008	Braeburn	2	193	10.7	1800	7	3	whole fruit	0.09	< 0.01	< 0.01
							7		<u>0.07</u>	< 0.01	< 0.01
							14		0.06	< 0.01	< 0.01
							28		0.06	< 0.01	< 0.01
		4	96	5.33	1800	7	3		0.08	< 0.01	< 0.01
							7		0.06	< 0.01	< 0.01
							14		0.05	< 0.01	< 0.01
							28		0.06	< 0.01	< 0.01
Havelock North, New Zealand, 2008	Royal Gala	2	198	16.5	1200	7	7	whole fruit	0.10	< 0.01	< 0.01
		4	98	8.17	1200	7	7		0.055	< 0.01	< 0.01
Nelson, New Zealand, 2008	Butte	2	193	16.1	1200	7	7	whole fruit	<u>0.065</u>	< 0.01	< 0.01
		4	98	8.17	1200	7	7		0.09	< 0.01	< 0.01
Motueka, New Zealand, 2008	Monterey	2	193	12.9	1500	7	7	whole fruit	<u>0.02</u>	< 0.01	< 0.01
		4	97	6.47	1500	7	7		0.05	< 0.01	< 0.01
Jork, Germany, EU, 2008	Jonagold	2	203	20.1	1010	6	3	whole fruit	0.24	< 0.01	< 0.01
							7		<u>0.18</u>	< 0.01	< 0.01
							14		0.18	< 0.01	< 0.01
							27		0.10	< 0.01	< 0.01
Wielonek, Poland, EU, 2008	Idared	2	202	10.1	1010	7	7	whole fruit	<u>0.078</u>	< 0.01	< 0.01
Barboles, Spain, EU, 2008	Golden	2	210	20.2	1040	7	3	whole fruit	0.27	< 0.01	< 0.01
							7		<u>0.27</u>	< 0.01	< 0.01
							14		0.20	< 0.01	0.010
							28		0.18	< 0.01	0.012
Korifi, Greece, EU, 2008	Mutsu	2	200	20	1000	7	7	whole fruit	<u>0.074</u>	< 0.01	< 0.01
Hereford, PA, USA, 2008	Star Krimson	2	205	9.07	2260	8	7	whole fruit	<u>0.043</u>	< 0.01	< 0.01
							14		0.041	< 0.01	< 0.01
Hereford, PA, USA, 2010	Star Krimson	2	202	15.4	1310	6	8	whole fruit	<u>0.12</u>	< 0.01	< 0.01
							15		0.12	< 0.01	< 0.01
Blissfield, MI, USA, 2008	Reds	2	202	11.5	1750	7	4	whole fruit	0.059	0.009	< 0.01
							7		<u>0.040</u>	0.010	< 0.01
							14		0.025	0.010	< 0.01
							28		0.021	< 0.01	< 0.01
Sanger, CA, USA, 2008	Pink Lady	2	204	14.3	1430	7	6	whole fruit	<u>0.064</u>	< 0.01	< 0.01
							14		0.050	0.011	< 0.01
Ephrata, WA, USA, 2008	Red Delicious	2	200	10.7	1870	7	7	whole fruit	<u>0.063</u>	< 0.01	< 0.01
							14		0.044	< 0.01	0.011
Royal City, WA, USA, 2008	Red Delicious	2	201	10.7	1880	7	7	whole fruit	<u>0.066</u>	< 0.01	< 0.01
							14		0.065	< 0.01	0.019

Location Year	Variety	Application				RTI	DAT	Portion	Residues (mg/kg)		
		No	g ai/ha	g ai/100L	L/ha				Sulfoxaflor	X11719474	X11721061
Orefield, PA, USA, 2010	Jonomac	2	202	15.4	1310	7	7 14	whole fruit	<u>0.072</u> 0.060	< 0.01 < 0.01	< 0.01 < 0.01
Moultrie, GA, USA, 2008	Red Fuji	2	202	19.8	1020	7	7 14	whole fruit	<u>< 0.01</u> < 0.01	< 0.01 < 0.01	< 0.01 < 0.01
Deerfield, MI, USA, 2010	Red Delicious	2	202	10.7	1890	7	7 14	whole fruit	<u>0.039</u> 0.024	< 0.01 < 0.01	< 0.01 < 0.01
Perry, UT, USA, 2010	Gala	2	201	15	1340	6	7 13	whole fruit	<u>0.089</u> 0.10	< 0.01 < 0.01	< 0.01 < 0.01
Caldwell, ID, USA, 2010	Honey Crisp	2	202	8.56	2360	6	6 14	whole fruit	<u>0.056</u> 0.045	< 0.01 < 0.01	< 0.01 < 0.01
Hood River, OR, USA, 2008)	Honey Crisp	2	202	8.86	2280	7	7 14	whole fruit	<u>0.068</u> 0.064	< 0.01 < 0.01	< 0.01 < 0.01

Pears

Table 7 Residue trials for sulfoxaflor in pears (Australia, Europe and USA)

Location Year	Variety	Application				RTI	DAT	Portion	Residues (mg/kg)		
		No	g ai/ha	g ai/100L	L/ha				Sulfoxaflor	X11719474	X11721061
Zeerust, Australia, 2009	Williams	2	194	10.8	1800	7	3	Whole fruit	0.12	< 0.01	0.010
							7		<u>0.11</u>	< 0.01	0.010
							14		0.060	< 0.01	< 0.01
							28		0.070	< 0.01	0.010
		4	96	5.33	1800	7	3	Whole fruit	0.14	< 0.01	0.010
							7		0.13	< 0.01	0.020
							14		0.080	< 0.01	0.020
							28		0.050	< 0.01	< 0.01
Paracombe, Australia, 2009	Packham Triumph	2	157	10.5	1500	7	7	Whole fruit	<u>0.22</u>	< 0.01	0.010
		4	80	5.33	1500	7	7	Whole fruit	0.18	0.010	0.020
Heidelberg-Kerchem, Germany, EU, 2008	Williams Christ	2	192	20.0	960	7	3	Whole fruit	0.10	< 0.01	< 0.01
							7		<u>0.058</u>	< 0.01	< 0.01
							14		0.055	< 0.01	< 0.01
							28		0.025	< 0.01	< 0.01
Mor, Hungary, EU, 2008	Pap korte	2	205	20.0	1020	7	7	Whole fruit	<u>0.052</u>	< 0.01	< 0.01
Nisi, Greece, EU, 2008	Williams	2	200	20.0	1000	7	7	Whole fruit	<u>0.18</u>	< 0.01	0.011
Alcarras, Spain, EU, 2008	Flor de invierno	2	213	13.4	1590	7	3	Whole fruit	0.074	< 0.01	< 0.01
							7		0.097	< 0.01	< 0.01
							14		<u>0.099</u>	< 0.01	< 0.01
							28		0.097	< 0.01	< 0.01

Location Year	Variety	Application				RTI	DAT	Portion	Residues (mg/kg)		
		No	g ai/ha	g ai/100L	L/ha				Sulfoxaflor	X11719474	X11721061
Gehrden, Germany, EU, 2010	Condo	2	193	20.0	970	7	0	Whole fruit	0.38	0.010	< 0.01
							3		0.13	< 0.01	< 0.01
							7		<u>0.10</u>	< 0.01	< 0.01
							14		0.10	< 0.01	< 0.01
							21		0.084	< 0.01	< 0.01
Malalbergo, Spain, EU, 2010	Abate	2	206	21.0	980	7	7	Whole fruit	<u>0.18</u>	< 0.01	< 0.01
Orefield, PA, USA, 2009	Bartlett	2	204	7.41	2750	7	3	Whole fruit	0.17	< 0.01	< 0.01
							8		<u>0.16</u>	< 0.01	< 0.01
							15		0.12	< 0.01	< 0.01
							21		0.097	< 0.01	< 0.01
Poplar, CA, USA, 2009	Olympic	2	204	13.6	1500	7	7	Whole fruit	<u>0.13</u>	< 0.01	< 0.01
							14		0.096	< 0.01	< 0.01
Lindsay, CA, USA, 2009	Red Olympic	2	202	9.84	2050	7	7	Whole fruit	<u>0.18</u>	< 0.01	< 0.01
							14		0.14	< 0.01	< 0.01
Ephrata, WA, USA, 2009	Concord	2	202	43.1	470	7	7	Whole fruit	0.26	< 0.01	0.017
							14		0.23	< 0.01	0.019
Ephrata, WA, USA, 2009	Star Bartlett	2	202	10.8	1870	7	7	Whole fruit	<u>0.23</u>	< 0.01	0.015
							14		0.18	< 0.01	0.015
Hood River, OR, USA, 2009	Red D'Anjou	2	202	13.1	1540	7	7	Whole fruit	0.075	< 0.01	< 0.01
							14		<u>0.078</u>	< 0.01	< 0.01

Stone fruits

Cherries

Table 8 Results of residue trials conducted with two (or four) applications of sulfoxaflor 240 g ai/L SC in/on cherry

Location Year	Variety	Application				RTI	DAT	Portion	Residues (mg/kg)		
		No	g ai/ha	g ai/100L	L/ha				Sulfoxaflor	X11719474	X11721061
Orange, N.S. Wales, AU, 2008	Merchant	2	193	9.65	2000	7	3	Pitted fruit	0.33	< 0.01	< 0.01
							7		<u>0.35</u>	< 0.01	< 0.01
							11		0.18	< 0.01	< 0.01
							14		0.17	< 0.01	< 0.01
							25		0.12	< 0.01	< 0.01
		4	98	4.9	2000	7	3		0.30	0.014	< 0.01
							7		0.37	0.013	< 0.01
							11		0.27	0.012	< 0.01
							14		0.24	0.010	< 0.01
							25		0.16	0.015	< 0.01
Havelock, N. NZ, NZ, 2008	Lapin	2	195	16.3	1200	7	7	Pitted fruit	<u>0.38</u>	< 0.01	0.013
									1.4	< 0.01	0.052
		4	97	8.08	1200	7	7	Pitted fruit	1.4	< 0.01	0.053
Frankfurt/Oder, DE, EU, 2008	Schatten- morelle	2	192	20.0	960	7	3	Pitted fruit	1.8	0.031	0.040
							7		<u>1.5</u>	0.029	0.048
							14		1.2	0.029	0.043
							21		0.96	0.031	0.044
Agárd, HU, EU, 2008	Kavics	2	194	20.0	970	7	7	Pitted fruit	<u>0.90</u>	0.011	0.017
Söllingen, DE, EU, 2009	Schatten- morelle	2	190	16.7	1140	7	7	Pitted fruit	<u>0.77</u>	0.011	< 0.01

Location Year	Variety	Application				RTI	DAT	Portion	Residues (mg/kg)		
		No	g ai/ha	g ai/100L	L/ha				Sulfoxaflor	X11719474	X11721061
Epila, ES, EU, 2008	Blanca	2	201	10.1	1990	7	7	Pitted fruit	<u>0.54</u>	0.010	0.026
Panagitsa, GR, EU, 2008	Mpakirtz-eika	2	202	16.7	1210	7	3	Pitted fruit	0.95	0.011	0.012
							7		<u>0.98</u>	0.014	0.016
							14		0.80	0.019	0.021
							21		0.73	0.021	0.022
Sahorre, FR, EU, 2008	Burlat	2	199	20.1	990	7	7	Pitted fruit	<u>0.80</u>	< 0.01	0.044
Orefield, PA, US, 2009	Montmorency	2	205	8.63	2380	7	6	Pitted fruit	<u>1.2</u>	0.016	0.026
Fennville, MI, US, 2009	Sour	2	202	21.0	960	7	7	Pitted fruit	<u>1.2</u>	0.013	0.048
Hart, MI, US, 2009	Sour	2	202	16.3	1240	7	7	Pitted fruit	<u>1.0</u>	0.016	0.042
Fennville, MI, US, 2009	Sweet	2	202	21.0	960	7	3	Pitted fruit	0.62	< 0.01	0.010
							7		<u>0.76</u>	< 0.01	0.018
							14		0.56	< 0.01	0.013
							21		0.35	< 0.01	0.012
Hart, MI, US, 2009	Sweet	2	202	16.3	1240	7	7	Pitted fruit	<u>0.59</u>	< 0.01	0.019
Marysville, CA, US, 2010	Brooks	2	204	16.2	1260	7	6	Pitted fruit	<u>0.55</u>	< 0.01	0.010

Nectarines

Table 9 Residue trials for sulfoxaflor in nectarines

Location Year	Variety	Application				RTI	DAT	Portion	Residues (mg/kg)		
		No	g ai/ha	g ai/100L	L/ha				Sulfoxaflor	X11719474	X11721061
Shepparton, Australia, 2009	Grand Sweet	2	192	16	1200	7	7	Pitted fruit	<u>0.12</u>	< 0.01	< 0.01
Ardmona, Australia, 2008	A38-039 Yellow	2	192	10.7	1800	8	3	Pitted fruit	0.27	< 0.01	< 0.01
							7		<u>0.18</u>	< 0.01	< 0.01
							14		0.13	< 0.01	< 0.01
							22		0.16	0.010	0.011
		4	96	5.33	1800	7	3	Pitted fruit	0.17	< 0.01	< 0.01
							7		0.14	0.011	< 0.01
							14		0.12	0.010	0.061
							22		0.15	0.013	0.010
Orange, Australia, 2008	Fairlane	2	195	9.75	2000	7	7	Pitted fruit	<u>0.14</u>	< 0.01	0.010
		4	87	4.85	2000	7	7	Pitted fruit	<u>0.16</u>	< 0.01	0.010
Karragullen, Australia, 2008	Red Gold	2	197	19.7	1000	7	7	Pitted fruit	<u>0.10</u>	< 0.01	< 0.01
		4	98	9.8	1000	7	7	Pitted fruit	0.23	0.010	0.015
Havelock, New Zealand, 2008	Red Gold	2	195	13	1500	7	7	Pitted fruit	<u>0.11</u>	< 0.01	0.014
		4	98	6.53	1500	7	7	Pitted fruit	0.19	< 0.01	0.021

Peaches

Table 10 Results of residue trials conducted with two (or four) applications of sulfoxaflor 240 g ai/L SC in/on peach

Location Year	Variety	Application				RTI	DAT	Portion	Residues (mg/kg)		
		No	g ai/ha	g ai/100L	L/ha				Sulfoxaflor	X11719474	X11721061
Shepparton, Victoria, Australia, 2008	Taylor Queen	2	194	10.8	1800	7	3 7 14 28	Pitted fruit	0.34 0.22 0.20 <u>0.24</u>	< 0.01 < 0.01 < 0.01 0.011	< 0.01 < 0.01 < 0.01 0.013
		4	97	5.4	1800	7	3 7 14 28		0.22 0.16 0.23 0.14	< 0.01 < 0.01 < 0.01 < 0.01	< 0.01 < 0.01 0.011 < 0.01
		2	194	9.7	2000	7	7		<u>0.27</u>	< 0.01	0.021
		4	98	4.9	2000	7	7		0.13	< 0.01	0.014
		2	190	19	1000	7	7		<u>0.15</u>	< 0.01	0.010
		4	97	9.7	1000	7	7		0.15	< 0.01	0.018
		2	192	10.7	1800	7	7		<u>0.14</u>	< 0.01	< 0.01
		4	97	5.4	1800	7	7		0.10	< 0.01	< 0.01
Ballandean, Queensland, Australia, 2009	Diamond Princess	2	194	19.4	1000	7	7	Pitted fruit	<u>0.012</u>	< 0.01	< 0.01
Shadforth, New South Wales, Australia, 2010	O'Henry	2	198	19.8	1000	7	3 7 14	Pitted fruit	0.18 0.10 <u>0.11</u>	< 0.01 < 0.01 < 0.01	0.022 0.010 0.014
		2	199	16.6	1200	7	8		<u>0.12</u>	< 0.01	0.010
		2	192	16	1200	7	7		<u>0.11</u>	< 0.01	0.016
Szekesfehervar, Hungary, EU, 2008	Padana	2	198	20	990	7	3 8 14 21	Pitted fruit	0.64 0.36 0.22 0.14	< 0.01 < 0.01 < 0.01 < 0.01	0.040 0.029 0.024 0.019
		2	197	22.2	890	7	7		0.20	< 0.01	0.010
		2	203	20.0	1020	7	7		0.54	0.010	0.022
		2	202	9.99	2020	7	3 7 14 21		0.49 0.27 0.25 0.12	< 0.01 < 0.01 < 0.01 < 0.01	0.017 0.017 0.018 0.013
Barbiano, Italy, EU, 2008	Sweet Red	2	198	13.4	1480	7	7	Pitted fruit	0.21	< 0.01	< 0.01
Lakka, Greece, EU, 2009	Andross	2	210	13.4	1570	7	7	Pitted fruit	0.83	< 0.01	0.012
Orefield, PA, USA, 2008	Glen Glow	2	202	7.18	2820	7	7	Pitted fruit	0.90	< 0.01	< 0.01
Montezuma, GA, USA, 2008	Flame Prince	2	202	21.4	940	7	4 7 10 14	Pitted fruit	0.058 0.032 0.032 0.028	< 0.01 < 0.01 < 0.01 < 0.01	< 0.01 < 0.01 < 0.01 < 0.01

Location Year	Variety	Application				RTI	DAT	Portion	Residues (mg/kg)		
		No	g ai/ha	g ai/100L	L/ha				Sulfoxaflor	X11719474	X11721061
Barney, GA, USA, 2008	Suwane	2	202	21.0	960	7	7	Pitted fruit	0.054	< 0.01	< 0.01
Blissfield, MI, USA, 2008	TNR 31	2	202	10.1	1990	7	7	Pitted fruit	0.17	< 0.01	0.017
Vernon, TX, USA, 2008	Loring	2	203	17.1	1180	7	7	Pitted fruit	0.14	< 0.01	< 0.01
Sanger, CA, USA, 2008	Tra-Zee	2	203	14.3	1420	7	6	Pitted fruit	0.12	< 0.01	< 0.01

Apricots

Table 11 Results of residue trials conducted with two (or four) applications of sulfoxaflor 240 g ai/L SC in/on apricots

Location Year	Variety	Application				RTI	DAT	Portion	Residues (mg/kg)		
		No	g ai/ha	g ai/100L	L/ha				Sulfoxaflor	X11719474	X11721061
Shepparton, Victoria, Australia 2008	Trevatt	2	193	14.8	1300	7	0 3 7 10	Pitted fruit	0.70	< 0.01	0.026
									0.46	< 0.01	0.036
									<u>0.42</u>	0.011	0.039
									0.40	0.010	0.043
		4	97	7.5	1300	7	0 3 7 10	Pitted fruit	0.29	< 0.01	0.011
									0.22	< 0.01	0.011
									0.18	< 0.01	0.017
									0.28	< 0.01	0.024
Hastings, Hawkes Bay, New Zealand 2008	Sundrop	2	190	9.5	2000	7	7	Pitted fruit	<u>0.15</u>	< 0.01	< 0.01
		4	95	4.8	2000	7	7	Pitted fruit	0.17	< 0.01	< 0.01

Plums

Table 12 Results of residue trials conducted with two applications of sulfoxaflor 240 g ai/L SC in/on plum

Location Year	Variety	Application				RTI	DAT	Portion	Residues (mg/kg)		
		No	g ai/ha	g ai/100L	L/ha				Sulfoxaflor	X11719474	X11721061
Nashdale, Australia, 2009	Autumn Giant	2	192	19.2	1000	7	3 7 14 28	Fruit, pitted	0.040	< 0.01	< 0.01
									<u>0.020</u>	< 0.01	< 0.01
									< 0.01	< 0.01	< 0.01
									< 0.01	< 0.01	< 0.01
Blissfield, MI, USA, 2009	NS	2	208 [240 SC]	6.93	3000	7	1 3 7 14	Fruit, pitted	0.27	< 0.01	< 0.01
									0.27	< 0.01	< 0.01
									0.21	0.011	< 0.01
									<u>0.26</u>	0.014	< 0.01
		2	202 [500 WDG]	15.7	1280	7	1 3 7 14	Fruit, pitted	0.37	0.012	< 0.01
									0.39	0.014	< 0.01
									0.36	0.015	< 0.01
									0.31	0.017	< 0.01
Fresno, CA, USA, 2009	NE Flavor	2	203 [240 SC]	10.8	1880	7	7	Fruit, pitted	0.062	< 0.01	< 0.01

Location Year	Variety	Application				RTI	DAT	Portion	Residues (mg/kg)		
		No	g ai/ha	g ai/100L	L/ha				Sulfoxaflor	X11719474	X11721061
		2	202 [500 WDG]	10.8	1870	7	7	Fruit, pitted	<u>0.090</u>	< 0.01	< 0.01
Porterville, CA, USA, 2009	NE Fortune	2	203 [240 SC]	12.3 12.3	1650 1660	7	7	Fruit, pitted	0.044	< 0.01	< 0.01
		2	204 [500 WDG]	12.3	1660	7	7	Fruit, pitted	<u>0.066</u>	< 0.01	< 0.01
Monmouth, OR, USA, 2008	Moyer	2	200 [240 SC]	13.8	1450	7	7	Fruit, pitted	0.045	< 0.01 < 0.01	< 0.01 < 0.01
		2	201 [500 WDG]	13.8	1460	7	7	Fruit, pitted	<u>0.054</u>	< 0.01	< 0.01
Dinuba, CA, USA, 2008	Black Fryers	2	202 [240 SC]	10.6	1900	7	7	Fruit, pitted	<u>0.030</u>	< 0.01	< 0.01
		2	205 [500 WDG]	10.6	1940	7	7	Fruit, pitted	0.017	< 0.01	< 0.01
Lindsay, CA, USA 2009	Angelina's	2	202 [240 SC]	20.9	960	7	7	Fruit, pitted	<u>0.11</u>	< 0.01	< 0.01
		2	201 [500 WDG]	20.8	960	7	7	Fruit, pitted	0.11	< 0.01	< 0.01

*Tree nuts**Almonds*

Table 13 Residue trials for sulfoxaflor in almonds

Location Year	Variety	Application				RTI	DAT	Portion	Residues (mg/kg)		
		No	g ai/ha	L/ha					Sulfoxaflor	X11719474	X11721061
Sanger, CA USA 2008	Ne Plus	2	202	1280		7	7	nutmeat	< 0.01	< 0.01	< 0.01
Kerman, CA USA 2008	Carmels	2	205	1870		7	3 7 14 21	nutmeat	< 0.01 < 0.01 < 0.01 < 0.01	< 0.01 < 0.01 < 0.01 < 0.01	< 0.01 < 0.01 < 0.01 < 0.01
Visalia, CA USA 2008	Non-Pareil	2	200	1870		7	7	nutmeat	< 0.01	< 0.01	< 0.01
Madera, CA USA 2008	Non-Pareil	2	200	1880		7	7	nutmeat	0.012	< 0.01	< 0.01
Madera, CA USA 2008	Butte	2	203	1870		7	7	nutmeat	< 0.01	< 0.01	< 0.01
Terra Bella, CA 2008	Monterey	2	202	2980		7	7	nutmeat	< 0.01	< 0.01	< 0.01

Pecans

Table 14 Residue trials for sulfoxaflor in pecans

Location Year	Variety	Application					Portion	Residues (mg/kg)		
		No	g ai/ha	L/ha	RTI	DAT		Sulfoxaflor	X11719474	X11721061
Chula, GA, USA, 2009	Summer	2	202	1280	7	3 7 14 21	nutmeat	< 0.01 < 0.01 < 0.01 < 0.01	< 0.01 < 0.01 < 0.01 < 0.01	< 0.01 < 0.01 < 0.01 < 0.01
Scooterville, GA, USA, 2009	Summer	2	202	1280	7	7	nutmeat	< 0.01	< 0.01	< 0.01
Sycamore, GA, USA, 2009	Summer	2	202	1270	7	7	nutmeat	< 0.01	< 0.01	< 0.01
Lonoke, AR, USA, 2009	Native/Stuart	2	202	960	7	7	nutmeat	< 0.01	< 0.01	< 0.01
Madill, OK, USA, 2009	Desirable	2	204	1140	7	7	nutmeat	< 0.01	< 0.01	< 0.01
Claytonville, TX, USA, 2009	Choctaw	2	204	1140	7	7	nutmeat	< 0.01	< 0.01	< 0.01

Animal Feeds

Table 15 Results of residue trials conducted with two applications of sulfoxaflor 240 g ai/L SC in/on almond hulls in the USA in 2008

Location Year	Variety	Application					Portion	Residues (mg/kg)		
		No	g ai/ha	L/ha	RTI	DAT		Sulfoxaflor	X11719474	X11721061
Sanger, CA USA 2008	Ne Plus	2	202	1280	7	7	hulls	3.1	0.097	0.15
Kerman, CA USA 2008	Carmels	2	205	1870	7	3 7 14 21	hulls	2.1 1.7 2.2 1.6	0.032 0.033 0.043 0.039	0.09 0.093 0.13 0.13
Visalia, CA USA 2008	Non-Pareil	2	200	1870	7	7	hulls	1.5	0.039	0.078
Madera, CA USA 2008	Non-Pareil	2	200	1880	7	7	hulls	1.2	0.028	0.047
Madera, CA USA 2008	Butte	2	203	1870	7	7	hulls	1.5	0.028	0.090
Terra Bella, CA 2008	Monterey	2	202	2980	7	7	hulls	2.2	0.040	0.14

APPRAISAL

Sulfoxaflor was first evaluated for residues and toxicological aspects by the 2011 JMPR. The 2011 Meeting established an ADI of 0–0.05 mg/kg bw and an ARfD of 0.3 mg/kg bw. The 2011 Meeting established a residue definition of sulfoxaflor for both compliance and dietary risk assessment in both plant and animal commodities. The 2011 Meeting estimated a number of maximum residue levels prior to registration of sulfoxaflor in any country as a pilot project.

After the subsequent meeting of CCPR, the proposed MRLs for citrus fruits, pome fruits, stone fruits and tree nuts were held at Step 4 because the provisional GAP reviewed by JMPR differed from the GAP finally approved in the USA.

The 2014 Meeting received information on registered use patterns for citrus fruit, pome fruit, stone fruit and tree nuts from the manufacturer and the residue data for those crops evaluated by the 2011 Meeting are reconsidered here against the submitted GAPs.

Results of supervised residue trials on crops

Citrus Fruit—Grapefruit, Lemon and Oranges

Registered use patterns from Australia and the USA were submitted. Supervised trial data for citrus were available from Australia, Brazil, and the USA.

Australian GAP for citrus fruit is for application at 9.6 g ai/100L (maximum of two applications, maximum 192 g ai/ha/single application, 1 day PHI).

USA GAP for citrus fruit is for application at 96 g ai/ha (14 day retreatment interval, maximum of four applications maximum 298 g ai/ha/ year, 1 day PHI).

None of the citrus fruit trials were conducted in accordance with the USA GAP. The majority of the Australian trials in oranges and mandarins were conducted at Australian GAP, while USA trials in oranges, grapefruit and lemons approximated Australian GAP after scaling.

The Meeting considered that US and Australian citrus fruit growing practices are similar, and noted the 2013 Meeting General Consideration item number 2.8 (Guidance for Use of Residue Trial Data from Different Geographical Locations for Estimation of Pesticide Residue Levels).

The Meeting determined that trials for all fruit will be related to Australian GAP for citrus fruit. The Meeting decided to use the concept of proportionality to estimate residue levels in citrus fruit in comparison to the Australian GAP where required. Scaled results for citrus fruit were within a range of 0.67–2.2× GAP, within the acceptable range for use of proportionality. Scaled results are indicated by an (s).

Grapefruit

Residue trials were conducted in grapefruit in the USA, approximating the critical GAP in Australia after scaling.

The results for grapefruit at a 1-day PHI after 2× 15.1–19.4 g ai/100L applications were: 0.010, 0.013, 0.016, 0.024, 0.11, and 0.13 mg/kg.

Residues in whole grapefruit after scaling to the Australian GAP were ≤ 0.01 (×3, all s), 0.015 (s), 0.064 (s) and 0.066 (s) mg/kg, where (s) indicates a result scaled to account for application rates outside ± 25% of GAP.

Residues in pulp of grapefruit, in ranked order after scaling, were ≤ 0.01 (×3, all s) mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg for the subgroup shaddocks or pomelos. The Meeting noted that sulfoxaflor has systemic properties and considered that three edible portion data points was not sufficient for estimation of STMR and HR values. Therefore, the Meeting estimated an STMR of 0.0125 mg/kg and an HR of 0.066 mg/kg for sulfoxaflor in shaddocks or pomelos, based on the whole fruit data.

Lemons and limes

Residue trials were conducted in lemons in the USA, approximating the critical GAP in Australia after scaling.

Results for whole lemons at a 1-day PHI after $2 \times 16.2\text{--}21.2$ g ai/100L were: < 0.01 (2), 0.083, 0.11, and 0.29 mg/kg.

Residues in whole lemons after scaling to the Australian GAP where required were < 0.01 ($\times 2$, both s), 0.038 (s), 0.055 (s) and 0.17 (s) mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg for the subgroup lemons and limes, together with an STMR of 0.038 mg/kg, and an HR of 0.17 mg/kg.

Oranges and mandarins

Residue trials were conducted in oranges, in Australia approximating the critical GAP in Australia.

Residues of sulfoxaflor in whole oranges from the Australian trials at a 1-day PHI after $2 \times 6.4\text{--}20.2$ g ai/100L applications were: 0.09, 0.15, 0.16, 0.33, 0.41, and 0.43 mg/kg.

Scaled residues in whole oranges from the Australian trials with scaling to the Australian GAP where necessary were 0.09, 0.15, 0.19 (s), 0.24 (s), 0.33, and 0.43 mg/kg.

Residues trials were conducted in mandarins in Australia, at GAP.

Residues in whole mandarins from the Australian trials at a 1-day PHI after $2 \times 7.6\text{--}9.6$ g ai/100L applications were: 0.15, 0.28, 0.34, and 0.44 mg/kg.

The Meeting noted that the medians for the Australian datasets for oranges and mandarins differed by less than fivefold (medians differed by a factor of only $1.4 \times$). The similarity of the datasets was further confirmed by the Mann-Whitney U-test. The Meeting concluded that the orange and mandarin datasets were mutually supportive and agreed to combine them for the purpose of estimation of maximum residue levels for the subgroups oranges, sweet, sour and mandarins.

The combined Australian data set for oranges and mandarins is 0.09, 0.15 (2), 0.19, 0.24, 0.28, 0.33, 0.34, 0.43, and 0.44 mg/kg.

The Meeting estimated maximum residue levels of 0.8 mg/kg for the subgroup oranges, sweet, sour and the subgroup mandarins, together with STMR values of 0.26 mg/kg and HR values of 0.44 mg/kg.

The Meeting withdrew the previous maximum residue level recommendation of 0.9 mg/kg for sulfoxaflor in citrus fruit.

Pome fruit - Apples and Pears

Registered use patterns from Australia and the USA were submitted. Supervised trials data were available for apples and pears from Australia/ New Zealand, Europe, and the USA.

Australian GAP for pome fruit is for application at 9.6 g ai/100L (maximum of two applications, maximum 192 g ai/ha/ single application, 7 day PHI).

USA GAP for pome fruit is for application at 96 g ai/ha (7 day retreatment interval, maximum of four applications maximum 298 g ai/ha/ year, 7 day PHI).

The Meeting noted that none of the trials were conducted in accordance with the USA GAP, while a number of the trials from both Australia/New Zealand and the USA matched the Australian GAP.

The Meeting considered that the US and Australian pome fruit growing practices are similar, and noted the 2013 Meeting General Consideration item number 2.8.

The Meeting determined that trials for both apples and pears will be related to Australian GAP for pome fruit. The Meeting decided to use the concept of proportionality as appropriate to estimate residue levels in pome fruit in comparison to the Australian GAP (trials for which proportionality was used were within $1.3\text{--}2.2 \times$ GAP, within the acceptable range).

Residue trials were conducted in apples and pears in Australia/ New Zealand, approximating the GAP in Australia.

Results in apples and pears from the Australia/New Zealand trials at a 7-day PHI after 2× 9.1–16.1 g ai/100L applications were 0.02, 0.065, 0.07, 0.11, 0.14, 0.19, and 0.22 mg/kg.

Residues in apples and pears from the Australia/New Zealand trials were 0.015 (s), 0.039 (s), 0.07, 0.11, 0.14, 0.19, and 0.22 mg/kg (STMR = 0.11 mg/kg), where (s) indicates a result scaled to account for application rates outside ± 25% of GAP.

Residue trials were conducted in apples and pears in the EU. Results at a 7-day PHI after 2× 10.1–21.0 g ai/100L applications were: 0.052, 0.058, 0.074, 0.078, 0.099, 0.10, 0.18 (3), and 0.27 mg/kg.

Residues in apples and pears from the European trials scaled according to the Australian GAP are: 0.025 (s), 0.028 (s), 0.036 (s), 0.048 (s), 0.071 (s), 0.078, 0.082 (s), 0.082 (s), 0.086 (s), and 0.13 (s) mg/kg (STMR = 0.075 mg/kg).

Residue trials were conducted in apples and pears in the USA.

USA apple and pear results at a 7-day PHI after 2× 7.4–19.8 g ai/100L applications were: < 0.01, 0.039, 0.040, 0.043, 0.056, 0.063, 0.064, 0.066, 0.068, 0.072, 0.075, 0.089, 0.12, 0.13, 0.16, 0.18, and 0.26 mg/kg.

Residues in apples and pears from the USA trials scaled to the Australian GAP where necessary were < 0.01 (s), 0.039, 0.040, 0.043, 0.043 (s), 0.045 (s), 0.055 (s), 0.056, 0.057 (s), 0.063, 0.066, 0.068, 0.075 (s), 0.092 (s), 0.16, 0.18, and 0.23 mg/kg (STMR = 0.057 mg/kg).

The Meeting considered that the seven data points from the Australia/New Zealand apple and pear trials were not sufficient for estimation of a group maximum residue level for pome fruit. The Meeting noted that results from Europe and the USA relevant to the Australian GAP were available and combined the Australian, European and USA data sets:

- < 0.01, 0.015, 0.025, 0.028, 0.036, 0.039 (2), 0.040, 0.043, 0.043, 0.045, 0.048, 0.055, 0.056, 0.057, 0.063, 0.066, 0.068, 0.07, 0.071, 0.075, 0.078, 0.082 (2), 0.086, 0.092, 0.11, 0.13, 0.14, 0.16, 0.18, 0.19, 0.22, and 0.23 mg/kg

The Meeting estimated a maximum residue level of 0.3 mg/kg for sulfoxaflor in pome fruit, together with an STMR of 0.067 mg/kg and an HR of 0.23 mg/kg.

The Meeting withdrew the previous maximum residue level recommendation of 0.4 mg/kg for sulfoxaflor in pome fruit.

Stone Fruit

Registered use patterns from Australia and the USA were submitted. Supervised trial data were available for apricot (Australia and New Zealand), cherries (Australia, EU and USA), nectarine (Australia and New Zealand), peach (Australia, EU and USA) and plums (Australia and USA).

Australian GAP for stone fruit is for application at 7.2 g ai/100L (maximum of two applications, maximum 144 g ai/ha/ single application, 7-day PHI).

USA GAP for stone fruit is for application at 96 g ai/ha (7-day retreatment interval, maximum of four applications maximum 298 g ai/ha/ year, 7-day PHI).

Insufficient trials were conducted in accordance with the USA GAP, while a significantly greater number were conducted in accordance with the Australian GAP, and further trials could be related to the Australian GAP through the use of proportionality (trials for which results were scaled were within 1.3–2.9× of GAP, within the acceptable range).

The Meeting considered that the US and Australian stone fruit growing practices are similar, and noted the 2013 Meeting General Consideration item number 2.8.

Therefore trials for all stone fruit will be related to the Australian GAP for stone fruit.

Cherries subgroup

A total of 14 trials on cherries were available from Australia/ New Zealand (1 each), Europe (6), and USA (6).

Australia/New Zealand cherry results at a 7-day PHI after $2 \times 9.7\text{--}16.3$ g ai/100L applications were 0.35 and 0.38 mg/kg.

Residues of sulfoxaflor in cherries from Australia were: 0.17 (s) and 0.35 mg/kg (STMR = 0.26 mg/kg) where (s) indicates a result scaled to account for application rates outside $\pm 25\%$ of GAP.

European cherry results at a 7-day PHI after $2 \times 10.1\text{--}20.1$ g ai/100L applications were: 0.54, 0.77, 0.80, 0.90, 0.98 and 1.5 mg/kg.

Residues of sulfoxaflor measured in cherries from in Europe in accordance with Australian GAP (scaled where necessary) were: 0.29 (s), 0.32 (s), 0.33 (s), 0.38 (s), 0.42 (s), and 0.54 (s) mg/kg (STMR = 0.355 mg/kg).

USA cherry results at a 7-day PHI after $2 \times 8.6\text{--}21.0$ g ai/100L applications were: 0.55, 0.59, 0.76, 1.0, and 1.2 (2) mg/kg.

Residues of sulfoxaflor in cherries from USA in accordance with the Australian GAP (scaled where necessary) were: 0.24 (s), 0.26 (s), 0.26 (s), 0.42 (s), 0.46 (s) and 1.2 mg/kg (STMR = 0.34 mg/kg).

The Meeting noted that there were insufficient residue trials conducted in Australia/New Zealand in accordance with the Australian GAP, and combined the Australia, American and European datasets for the purpose of estimating a maximum residue level for the cherries subgroup.

Residues in cherries from trials conducted in Australia/New Zealand, EU countries and the USA were:

- 0.17, 0.24, 0.26 (2), 0.29, 0.32, 0.33, 0.35, 0.38, 0.42 (2), 0.46, 0.54, and 1.2 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg for the subgroup cherries, together with an STMR of 0.34 mg/kg, and an HR of 1.24 mg/kg (unrounded result).

Peaches subgroup

A total of five trials on nectarines were available from Australia and New Zealand. The results for nectarines at a 7-day PHI after $2 \times 9.8\text{--}19.7$ g ai/100L applications were: 0.10, 0.11, 0.12, 0.14, and 0.18 mg/kg.

Residues of sulfoxaflor in nectarines from Australia and New Zealand were: 0.037 (s), 0.054 (s), 0.061 (s), 0.10 (s) and 0.12 (s) mg/kg (STMR = 0.061 mg/kg) where (s) indicates a result scaled to account for application rates outside $\pm 25\%$ of GAP.

Two trials on apricots were available from Australia and New Zealand. The results for apricots at a 7-day PHI after $2 \times 9.5\text{--}14.8$ g ai/100L applications were: 0.15 and 0.42 mg/kg.

Residues of sulfoxaflor apricots from Australia/New Zealand in accordance with the Australian GAP (scaled where necessary) were: 0.11 (s) and 0.20 (s) mg/kg (STMR = 0.155 mg/kg).

Eight trials in peaches were conducted in Australia and New Zealand. The results at a 7-day PHI after $2 \times 9.7\text{--}19.8$ g ai/100L applications were: 0.012, 0.11, 0.11, 0.12, 0.14, 0.15, 0.24, and 0.27 mg/kg.

Residues of sulfoxaflor in peaches from Australia and New Zealand (scaled to the Australian GAP where required) were: < 0.01 (s), 0.040 (s), 0.050 (s), 0.052 (s), 0.057 (s), 0.094 (s), 0.16 (s) and 0.20 (s) mg/kg (STMR = 0.0545 mg/kg).

The Meeting noted that the GAP under consideration is for Australia, and that a large regional (Australia/New Zealand) data set for the peach group is available (15 trials in total for peaches, nectarines and apricots), and that the median values of these data sets are within a factor of $5 \times$ each

other (the medians differed by a maximum factor of 2.8×). The Meeting agreed to combine the Australia/New Zealand peach, nectarine and apricot data for the purpose of estimating a maximum residue level for the peach subgroup:

- < 0.01, 0.037, 0.04, 0.05, 0.052, 0.054, 0.057, 0.061, 0.094, 0.10, 0.11, 0.12, 0.16, and 0.20 (2) mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg for the subgroup peaches, together with an STMR of 0.061 mg/kg and an HR of 0.2 mg/kg.

Plums

A total of seven trials on plums were available from Australia (1) and USA (6).

The Australian result for plums at a 7-day PHI after 2× 19.2 g ai/100L applications was: 0.020 mg/kg.

Residues of sulfoxaflor measured in plums from Australia were: < 0.01 (s) mg/kg where (s) indicates a result scaled to account for application rates outside ± 25% of GAP.

The USA results for plums at a 7-day PHI after 2× 6.9–20.9 g ai/100L applications were: 0.030, 0.054, 0.066, 0.090, 0.11, and 0.26 mg/kg.

Residues of sulfoxaflor in plums from the USA in accordance with the Australian GAP (scaled where necessary) were: 0.020 (s), 0.028 (s), 0.038 (s), 0.039 (s), 0.06 (s) and 0.26 mg/kg.

Residues in plums from trials conducted in Australia and the USA were: < 0.01, 0.020, 0.028, 0.038, 0.039, 0.06, and 0.26 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg for the subgroup plums, together with an STMR of 0.038 mg/kg, and an HR of 0.26 mg/kg.

The Meeting withdrew the previous maximum residue level recommendation of 3 mg/kg for sulfoxaflor in stone fruit.

Tree Nuts

USA GAP for tree nuts (Crop Group 14) including almonds, cashew, chestnut, hazelnut, macadamia, pecan and walnut is for application at 96 g ai/ha (7 day retreatment interval, maximum of four applications maximum 298 g ai/ha/ year, 7 day PHI).

Residues data from trials conducted in the USA were available for almonds and pecans. However, the trials do not match the USA GAP, with only two applications being made at a rate of 200–205 g ai/ha with a 7-day PHI. The Meeting therefore did not estimate maximum residue levels, STMRs or HRs for the tree nut group.

The Meeting agreed to withdraw the previous maximum residue level recommendation of 0.015 mg/kg for sulfoxaflor in tree nuts.

Animal feeds

Almond hulls

Residue data for sulfoxaflor in almond hulls were available to the Meeting. However, as the trials were not conducted in accordance with the USA GAP for almonds, the Meeting did not estimate a median residue value.

Fate of residues during processing

The 2011 Meeting received information on the fate of sulfoxaflor residues during the processing of apple to juice, sauce and wet and dry pomace; cherry to dried cherries, jam and juice and oranges to juice, wet and dry pulp, oil and peel.

Calculated processing factors are summarized in the following table based on the JMPR 2014 recommendations for MRLs and STMRs. Factors are indicated with a '<' (less-than) sign when the residue in the processed commodity is below the LOQ of the analytical method. The calculation is then made on the LOQ of the analytical method and the residue concentration of the RAC (raw agricultural commodity).

Processes included in the table are those that lead to STMR-P or HR-P values useful for dietary intake estimations or for livestock dietary burden calculations.

Raw Agricultural Commodity (RAC)	Processed Commodity	Best Estimate Processing Factor (PF)	RAC MRL (mg/kg)	RAC STMR (mg/kg)	RAC HR (mg/kg)	Processed commodity STMR-P (mg/kg)	Processed commodity HR-P (mg/kg)
Apple	Wet pomace	1.1	0.3	0.067	0.23	0.074	–
	Dry pomace	4.2				0.28	–
	Juice	0.4				0.027	–
	Sauce	0.6				0.040	–
Cherry	Juice	0.8	1.5	0.34	1.24	0.27	–
	Jam	1.1				0.37	–
	Dried	5.1				1.73	6.32
Orange	Juice	0.14	0.8	0.26	0.44	0.036	–
	Wet pulp	2.5				0.65	–
	Dried pulp	8.3				2.16	–
	Oil	< 0.2				< 0.052	–
	Peel	5.6				1.46	2.45

Animal commodities

The Meeting recalculated the livestock dietary burden based on the uses considered by the current Meeting and by the 2011 Meeting on the basis of diets listed in the FAO Manual Appendix IX (OECD Feedstuff Table).

The maximum dietary burden is 3.22 ppm for beef and dairy cattle, while the mean dietary burden is 1.26 ppm for beef and dairy cattle. The values calculated by the 2011 Meeting were: maximum dietary burden of 3.04 ppm for beef cattle and 2.68 ppm for dairy cattle, and a mean dietary burden of 0.91 ppm for both dairy and beef cattle. Interpolation of these values between the appropriate feeding levels in the lactating cattle feeding study considered by the 2011 Meeting showed that no changes to the maximum residue levels estimated by the 2011 Meeting for milks, edible offal (mammalian) or meat (from mammals other than marine mammals) were required.

The maximum and mean dietary burdens for poultry (both layers and broilers) are 0.93 and 0.31 ppm respectively. These have changed very little from the values determined by the 2011 Meeting (maximum and mean values of 0.89 and 0.30 ppm respectively).

The Meeting confirmed its previous recommendations for meat (from mammals other than marine mammals), edible offal (mammalian), milks, poultry meat, poultry, edible offal of, and eggs.

The Meeting noted that the 2011 Meeting did not estimate maximum residue levels for mammalian fats (except milk fats) or poultry fats.

The Meeting noted the STMR values of 0.03 mg/kg and HR value of 0.073 mg/kg estimated by the 2011 Meeting for the fat compartment of mammalian meat (from mammals other than marine mammals). Noting that the dietary burden has not significantly increased, the Meeting estimated a maximum residue level of 0.1 mg/kg for mammalian fats (except milk fats), together with an STMR of 0.03 mg/kg and an HR of 0.073 mg/kg.

The Meeting noted the STMR values of 0.005 mg/kg and HR value of 0.021 mg/kg estimated by the 2011 Meeting for the fat compartment of poultry meat. Noting that the dietary burden has not significantly increased, the Meeting estimated a maximum residue level of 0.03 mg/kg for poultry fats, together with an STMR of 0.005 mg/kg and an HR of 0.021 mg/kg.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI assessment.

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: *sulfoxaflor*

The residue is not fat soluble

The Meeting estimated the maximum residue levels and STMR values shown below.

Commodity		MRL, mg/kg		STMR or STMR-P, mg/kg	HR or HR-P, mg/kg
CCN	Name	New	Previous		
FS 0013	Cherries	1.5	–	0.34	1.24
FC 0001	Citrus fruits	W	0.9	–	–
FC 0002	Lemons and limes	0.4	–	0.038	0.17
FC 0003	Mandarins	0.8	–	0.26	0.44
MF 0100	Mammalian fats (except milk fats)	0.1	–	0.03	0.073
FC 0004	Oranges, Sweet, Sour	0.8	–	0.26	0.44
FS 2001	Peaches	0.4	–	0.061	0.20
FS 0014	Plums	0.5	–	0.038	0.26
FP 0009	Pome fruits	0.3	0.4	0.067	0.23
PF 0111	Poultry fats	0.03	–	0.005	0.021
FC 0005	Pomelos and Grapefruit	0.15	–	0.0125	0.066
FS 0012	Stone fruits	W	3	–	–
TN 0085	Tree nuts	W	0.015	–	–
	Apple juice			0.027	–
	Apple sauce			0.040	–
	Cherry juice			0.27	–
	Cherry jam			0.37	–
	Cherry, dried			1.73	6.32
	Orange juice			0.036	–
	Orange oil			< 0.052	–
	Orange peel			1.46	2.46

Commodity		STMR or STMR-P, mg/kg	HR or HR-P, mg/kg
CCN	Name		
–	Apple pomace, wet	0.074	–
–	Apple pomace, dry	0.28	–
–	Citrus dried pulp	2.16	–

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of sulfoxaflor has resulted in recommendations for MRLs and STMRs for raw and processed commodities. The International Estimated Daily Intakes for the 17 GEMS/Food cluster diets, based on estimated STMRs were in the range 1–7% of the maximum ADI of 0.05 mg/kg bw (Annex 3 of the 2014 Report).

The Meeting concluded that the long-term intake of residues of sulfoxaflor, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intake (IESTI) for sulfoxaflor was calculated for the plant and livestock commodities (and their processing fractions) for which new STMRs and HRs were

estimated and for which consumption data were available. The results are shown in Annex 4 to the 2014 Report.

The IESTI varied from 0–9 % of the ARfD (0.3 mg/kg bw). The Meeting concluded that the short-term intake of residues of sulfoxaflor, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

Author(s)	Year	Title, Source , Report No., Date,
Bacher, R.	2006	Independent laboratory validation of Bayer CropScience method No. 01009 for the determination of residues of JAU 6476-desthio, JAU 6476-3-hydroxy-desthio, JAU 6476-4-hydroxy-desthio, JAU 6476-3,4-dihydroxy-desthio, and JAU 6476-4,5-...PTRL Europe GmbH, Ulm, Germany, BCS, Report No.: P/B 1111 G, Edition Number: M-279818-01-1, Method Report No.: P613060597 Date: 2006-11-02, GLP/GEP: yes, unpublished.
Brumhard, B.; Stuke, S.	2007	Analytical method 01013 for the simultaneous determination of residues of the active Items BYF00587, prothioconazole, tebuconazole, trifloxystrobin and the metabolites BYF00587-desmethyl, JAU6476-desthio (SXX0665) and CGA321113 in/on ...Bayer CropScience, Report No.: 01013, Edition Number: M-283439-03-1 Method Report No.: MR-06/138 Date: 2007-01-25, ...Amended: 2008-02-18, GLP/GEP: yes, unpublished.
Ellis, A.	2012	Determination of residues of prothioconazole in peanut kernels, shells and fodder following three, four or five applications of Proline (JAU 6476) 480 SC at rates of 120 or 180 g a.i./ha at ten day intervals up to 14 days before harvest, Bayer CropScience Residue Laboratory, Brisbane, QLD, Australia, Report No.: BCS-0232, Report includes Trial Nos.: C351, C352, C353, C354, Edition Number: M-437933-01-1, Date: 2012-09-06, GLP/GEP: yes, unpublished.
Gould, T. J.; Timberlake, B. C.; Krolski, M. E.; Nguyen, S.; Moore, S.	2003	Bayer CropScience analytical method RPA JA/03/01: JAU6476: An analytical method for the determination of residues of JAU6476 and desthio-JAU 6476 in plant matrices using LC/MS-MS, Bayer CropScience LP, Stilwell, KS, USA, Bayer CropScience, Report No.: RPA JA/03/01, Edition Number: M-003024-01-1, Method Report No US: 200799, Method Report No US: RPA JA/03/01, GLP/GEP: yes, unpublished.
Gould, T. J.; Timberlake, B. C.	2010	An analytical method for the determination of residues of prothioconazole and desthio-prothioconazole in plant matrices using LC-MS/MS, Bayer CropScience LP, Stilwell, KS, USA, Bayer CropScience, Report No.: JA-001-P04-02, Edition Number: M-362015-01-1, EPA MRID No.: 47948901 Date: 2010-01-08, GLP/GEP: no, unpublished.
Gould, T. J.; Timberlake, B. C.	2008	Storage stability of prothioconazole in canola, wheat, mustard greens, turnip root, and tomato fruit, and processed products. Bayer CropScience LP, Stilwell, KS, USA, Bayer CropScience, Report No.: RAJAY016, Edition Number: M-300712-01-1, EPA MRID No.: 47408201, Date: 2008-04-18, GLP/GEP: yes, unpublished.
Heinemann, O.	2000	Analytical determination of residues of JAU6476 and JAU6476-desthio in/on cereals and canola by HPLC-MS/MS (method modification 00598/M001), Bayer AG, Leverkusen, Germany, Bayer CropScience, Report No.: 00598/M001, Edition Number: M-047681-01-1, Method Report No.: MR-689/99, EPA MRID No.: 46477703, GLP/GEP: yes, unpublished.
Schulte, G.; Oel, D.	2006	Analytical method 01009 for the determination of residues of JAU 6476-desthio, JAU 6476-3-hydroxy-desthio, JAU 6476-4-hydroxy-desthio, JAU 6476-3,4-dihydroxy-desthio, and JAU 6476-4,5-dihydroxy-desthio in/on matrices of animal origin by .Bayer CropScience, Report No.: MR-06/120, Edition Number: M-279725-02-1, Method Report No.: MR-06/120, Date: 2006-10-26, .Amended: 2013-01-25, GLP/GEP: yes, unpublished.
Bomke, S.; Bauer, J.	2011	Determination of the residues of penflufen and prothioconazole in/on potato after seed treatment, general of BYF 14182 & Prothioconazole FS 118 in the field in Germany, France (North), Belgium and the Netherlands, Bayer CropScience, Report No.: 10-2085, Report includes Trial Nos.: 10-2085-01, 10-2085-02, 10-2085-03, 10-2085-04, Edition Number: M-410267-02-1, Date: 2011-06-29, .Amended: 2011-07-25, GLP/GEP: yes, unpublished.
Bomke, S.	2012	Determination of the residues of AE C656948 and prothioconazole in/on maize/corn after spray application of AE C656948 & JAU 6476 SE 250 in southern France, Italy, Spain and Greece, Bayer CropScience, Report No.: 11-2110, Report includes Trial Nos.: 11-2110-02, 11-2110-03, 11-2110-04, 11-2110-05. Edition Number: M-442647-01-1, Date: 2012-11-28, GLP/GEP: yes, unpublished.

Author(s)	Year	Title, Source , Report No., Date,
Duah, F. K.; Harbin, A. M.	2006	JAU6476 480 SC - Magnitude of the residue in/on soybeans, Pyxant Labs, Inc., Colorado Springs, CO, USA, Bayer CropScience, Report No.: RAJAY026, Edition Number: M-270206-01-1, EPA MRID No.: 46841001, Date: 2006-04-28. GLP/GEP: yes, unpublished.
Ellis, A.	2012	Determination of residues of prothioconazole in peanut kernels, shells and fodder following three, four or five applications of Proline (JAU 6476) 480 SC at rates of 120 or 180 g a.i./ha at ten day intervals up to 14 days before harvest, Bayer CropScience Residue Laboratory, Brisbane, QLD, Australia, Report No.: BCS-0232, Report includes Trial Nos.:C351, C352, C353, C354. Edition Number: M-437933-01-1, Date: 2012-09-06. GLP/GEP: yes, unpublished.
Ellis, A.	2012	Determination of residues of prothioconazole in peanut kernels, shells and fodder following a range of applications of Rudis SC 480 at rates of 192 and 288 g a.i./ha at various timings. Bayer CropScience, Eight Mile Plains, QLD, Australia, Bayer CropScience, Report No.: BCS-0383, Report includes Trial Nos.: C668, C680, C682, C697, Edition Number: M-438813-01-1, Date: 2012-09-19, GLP/GEP: yes, unpublished.
Freitag, T.; Wolters, A.	2007	Determination of the residues of JAU 6476 and penycuron in/on potato after seed treatment of JAU 6476 & NTN 19701 (258 FS) in the field in the Netherlands, United Kingdom, Germany and Northern France, Bayer CropScience, Report No.: RA-2569/05, Report includes Trial Nos.: R 2005 0466/7 = 0466 - 05, R 2005 0873/5 = 0873 - 05, R 2005 0874/3 = 0874 - 05, R 2005 0875/1 = 0875 - 05, Edition Number: M-283397-01-1, Date: 2007-02-02, GLP/GEP: yes, unpublished.
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